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EXAMINER	
CHONG, KIMBERLY	
ART UNIT	**PAPER NUMBER**
1635	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/800,077	REDDY ET AL.	
	Examiner	Art Unit	
	Kimberly Chong	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-11,13,14,16,18-25,30-59,61-83 and 88-91* is/are pending in the application.

4a) Of the above claim(s) *18-25,30-58,61-83 and 88-91* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-11,13-14,16,59* is/are rejected.

7)☒ Claim(s) *14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: _____.

DETAILED ACTION

Status of Application/Amendment/Claims

Claims 15-17 in the previous office action mailed 10/31/2006 were indicated as allowable but objected to as being dependent upon a rejected base claim. Upon further consideration, these claims are not found allowable. Therefore, the finality of the previous office action mailed 10/31/2006 is withdrawn.

Applicant's response filed 04/27/2006 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 10/31/2006 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 10/31/2006, claims 1, 3, 5-11, 13-14, 16, 18-25, 30-59, 61-83, 88-91 are pending, claims 1, 3, 5-11, 13-14, 16 and 59 are currently under examination, claims 2, 4, 12, 15, 17, 26-29, 60 and 84-87 have been canceled and claims 18-25, 30-58, 61-83 and 88-91 are withdrawn as being drawn to a non-elected invention.

Election/Restrictions

Applicants continue to traverse the restriction requirement and reiterate the arguments already made of record. As stated in the previous Office action filed 04/03/2006, the restriction requirement was made FINAL for the reasons of record.

Claim Objections

Claim 14 is objected to as reciting non-elected subject matter. Claim 14 should be rewritten deleting any non-elected subject matter.

New Claim Rejections

Claim Rejections - 35 USC § 102 or 35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 5-7, 9-11, 13, 16 and 59 are rejected under 35 U.S.C. 102(b) or 35 U.S.C. 103(a) as being anticipated by or obvious over Bennett et al. (cited on PTO 892 mailed 10/31/2006).

The claims are drawn to an isolated nucleic acid compound comprising at least a portion that is complementary to at least 15 contiguous nucleotides of an EphB4 transcript, wherein the EphB4 transcript has a nucleotide sequence set forth in SEQ ID NO: 392, wherein the nucleic acid compound comprises a nucleotide sequence that is

complementary to a region consisting of not more than 500 nucleotides of SEQ Id NO: 392, wherein the nucleic acid compound is from about 15 to about 75 nucleotides in length, wherein the compound is single-stranded, a DNA molecule, a RNA molecule or DNA strand and an RNA strand modified or is an antisense nucleic acid, wherein the compound comprises one modified backbone or base moieties, wherein the compound has at least one internucleotide linkage, wherein the compound comprises at least one 2'-O-alkylated ribonucleotide and drawn to pharmaceutical composition comprising said nucleic acid compound.

Bennett et al. teach an antisense compound, 18 nucleobases in length, that is complementary to at least 15 contiguous nucleotides of EphB4 set forth in SEQ ID NO: 392 (see attached sequence alignment and SEQ ID NO: 94). Bennett et al. teach the compound is single-stranded, a DNA molecule or a RNA molecule (see column 5, lines 35-45), wherein the compound comprises one modified backbone or base moieties, wherein the compound has at least one internucleotide linkage (column 6), wherein the compound comprises at least one 2'-O-alkylated ribonucleotide (see columns 7-8). Bennett et al. teach pharmaceutical compositions comprising said nucleic acid compounds (see column 12, lines 30-65).

Therefore, the nucleic acid sequence taught by Bennett *et al.* meets the structural limitation of claims 1, 3, 5-7, 9-11, 13 and 59 of the instant application and would be expected to hybridize to a nucleic acid encoding of EphB4 and decrease expression of EphB4 in a cell. See, for example, MPEP 2112, which states "[w]here applicant claims a composition in terms of a function, property or characteristic and the

composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic.

Although Bennett et al. does not explicitly disclose said antisense compound would decrease the expression of EphB4 in cells, the antisense compound taught by Bennett et al. is structurally identical to the claimed nucleic acid compound and therefore the claimed function of decreasing the expression of EphB4 would be an inherent property. The instantly claimed antisense compound is required to have at least a portion that is complementary to at least 15 contiguous nucleotides of an EphB4 transcript and thus decrease expression of EphB4. Bennett et al. teach antisense compounds wherein at least 15 contiguous nucleotides are complementary to the open reading frame of EphB4 having SEQ ID NO. 392 and Bennett et al teach that an antisense compound that hybridizes effectively to the open reading frame of a target gene would function to interfere with expression of said target gene (see columns 3 and 4). Bennett et al. further state antisense compounds are routinely used as therapeutic agents to interfere with expression from target nucleic acids in cells.

Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims and the instant claims are anticipated or is obvious over Bennett et al.

Claims 1, 3, 5-8, 10-11, 13, 16 and 59 are rejected under 35 U.S.C. 102(e) or 35 U.S.C. 103(a) as being anticipated by or obvious over Khvorova et al. (cited on PTO 892 mailed 10/31/2006).

The claims are drawn to an isolated nucleic acid compound comprising at least a portion that hybridizes to an EphB4 transcript, wherein the EphB4 transcript has a nucleotide sequence set forth in SEQ ID NO: 392, wherein the nucleic acid compound comprises a nucleotide sequence that is complementary to a region consisting of n more than 500 nucleotides of SEQ Id NO: 392, wherein the region has at least 8 contiguous nucleotides of the SEQ ID NO: 392, wherein the nucleic acid compound is from about 15 to about 75 nucleotides in length, wherein the compound is single-stranded, double-stranded, a DNA molecule, a RNA molecule or DNA strand and an RNA strand modified or is an antisense nucleic acid, wherein the compound comprises one modified backbone or base moieties, wherein the compound has at least one internucleotide linkage, wherein the compound comprises at least one 2'-O-alkylated ribonucleotide, wherein the compound is an enzymatic nucleic acid, wherein the enzymatic compound is a ribozyme, wherein the enzymatic nucleic acid is a DNA enzyme and drawn to pharmaceutical composition comprising said nucleic acid compound.

Khvorova et al. teach a dsRNA compound, 19 nucleobases in length that is complementary to at least 15 contiguous nucleotides of EphB4 set forth in SEQ ID NO: 392 (see attached sequence alignment and SEQ ID NO: 4253). Khvorova et al. teach the compound is single-stranded that can form a hairpin loop or a double-stranded RNA molecule (see paragraph 0109), wherein the compound comprises one modified backbone or base moieties, wherein the compound has at least one internucleotide linkage, wherein the compound comprises at least one 2'-O-alkylated ribonucleotide (see paragraphs 0136-0138). Khvorova et al. teach pharmaceutical compositions comprising said nucleic acid compounds (see paragraphs 0316). Therefore, the nucleic acid sequence taught by Khvorova *et al.* meets the structural limitation of claims 1, 3, 5-8, 10-11, 13 and 59 of the instant application and would be expected to hybridize to a nucleic acid encoding of EphB4. See, for example, MPEP 2112, which states "[w]here applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims.

Although Khvorova et al. does not explicitly disclose said antisense compound would decrease the expression of EphB4 in cells, the antisense compound taught by Khvorova et al. is structurally identical to the claimed nucleic acid compound and therefore the claimed function of decreasing the expression of EphB4 would be an inherent property. The instantly claimed antisense compound is required to have at least a portion that is complementary to at least 15 contiguous nucleotides of an EphB4 transcript and thus decrease expression of EphB4. Khvorova et al. teach said nucleic acid compound binds to a target gene and attenuate the expression from said nucleic acid target (see column 5-6) that a nucleic acid compound comprises an antisense compound that contains a region that specifically binds to a target nucleic acid and has RNA cleavage enzymatic activity to effectively inhibit nucleic acid expression of a target gene (see column 4).

Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims and the instant claims are anticipated or is obvious over Khvorova et al.

Claims 1, 3, 5-11, 13 and 59 are rejected under 35 U.S.C. 102(e) or 35 U.S.C. 103(a) as being anticipated by or obvious over Robbins et al. (cited on PTO 892 mailed 10/31/2006).

The claims are drawn to an isolated nucleic acid compound comprising at least a portion that hybridizes to an EphB4 transcript, wherein the EphB4 transcript has a nucleotide sequence set forth in SEQ ID NO: 392, wherein the nucleic acid compound

comprises a nucleotide sequence that is complementary to a region consisting of n more than 500 nucleotides of SEQ Id NO: 392, wherein the region has at least 8 contiguous nucleotides of the SEQ ID NO: 392, wherein the nucleic acid compound is from about 15 to about 75 nucleotides in length, wherein the compound is single-stranded, double-stranded, a DNA molecule, a RNA molecule or DNA strand and an RNA strand modified or is an antisense nucleic acid, wherein the compound comprises one modified backbone or base moieties, wherein the compound has at least one internucleotide linkage, wherein the compound comprises at least one 2'-O-alkylated ribonucleotide, wherein the compound is an enzymatic nucleic acid, wherein the enzymatic compound is a ribozyme, wherein the enzymatic nucleic acid is a DNA enzyme and drawn to pharmaceutical composition comprising said nucleic acid compound.

Robbins et al. teach a compound, 19 nucleobases in length that is complementary to at least 15 contiguous nucleotides of EphB4 set forth in SEQ ID NO: 392 (see attached sequence alignment and SEQ ID NO: 4253). Robbins et al. teach the compound is single-stranded, double-stranded, a DNA molecule or a RNA molecule (see Figure 6 and column 7 lines 15-35), wherein the compound comprises one modified backbone or base moieties, wherein the compound has at least one internucleotide linkage, wherein the compound comprises at least one 2'-O-alkylated ribonucleotide (see columns 5, lines 4-34). Robbins et al. teach pharmaceutical compositions comprising said nucleic acid compounds (see columns 9-10). Therefore, the nucleic acid sequence taught by Robbins *et al.* meets the structural limitation of

claims 1, 3, 5-11, 13 and 59 of the instant application and would be expected to hybridize to a nucleic acid encoding of EphB4. See, for example, MPEP 2112, which states "[w]here applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims.

Although Robbins et al. does not explicitly disclose said antisense compound would decrease the expression of EphB4 in cells, the antisense compound taught by Robbins et al. is structurally identical to the claimed nucleic acid compound and therefore the claimed function of decreasing the expression of EphB4 would be an inherent property. The instantly claimed antisense compound is required to have at least a portion that is complementary to at least 15 contiguous nucleotides of an EphB4 transcript and thus decrease expression of EphB4. Robbins et al. teach antisense compounds wherein at least 15 contiguous nucleotides are complementary to the open reading frame of EphB4 having SEQ ID NO. 392 and Robbins et al. teach that a nucleic acid compound comprises an antisense compound that contains a region that

specifically binds to a target nucleic acid and has RNA cleavage enzymatic activity to effectively inhibit nucleic acid expression of a target gene (see column 4).

Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims and the instant claims are anticipated or is obvious over Robbins et al.

The foregoing represents new rejections necessitated by the claim amendments filed 04/27/2007 however, response to applicant's arguments will be addressed since they would apply to the new rejections above.

Applicants argue neither Bennett et al., Khvorova et al. nor Robbins et al. teach antisense compounds for decreasing the expression of EphB4. Applicants further argue that Bennett et al. do not teach an antisense comprising a 2'-O-alkylated modification.

As stated above, the antisense compound taught by Bennett et al., Khvorova et al. and Robbins et al. are structurally identical to the claimed nucleic acid compound and therefore the claimed function of decreasing the expression of EphB4 would be an inherent property. Furthermore, as cited above and in the previous office action (see page 5 of action mailed 10/31/2006), Bennett et al. teach antisense compounds comprising at least one 2'-O-alkylated modification (see columns 7-8).

Thus, the instant clams are anticipated or obvious over Bennett et al., Khvorova et al. and Robbins et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 5-8, 10-11, 13-14, 16 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyagishi et al. (Oligonucleotides 2003, Vol. 13: 325-333), Promega (siRNA Designer Version 1.1, May 2003, www.promega.com), and Khvorova et al. (cited on PTO 892 mailed 10/31/2006).

The claims are drawn to an isolated nucleic acid compound comprising at least a portion that hybridizes to an EphB4 transcript, wherein the nucleic acid compound is an antisense compound, wherein the EphB4 transcript has a nucleotide sequence set forth in SEQ ID NO: 392, wherein the nucleic acid compound comprises a nucleotide sequence that is complementary to a region consisting of n more than 500 nucleotides of SEQ ID NO: 392 and wherein the antisense compound comprises the sequence set forth as SEQ ID No. 231.

It must be noted that an antisense nucleic acid is defined in the specification on page 21 as a non-enzymatic nucleic acid compound that binds to a target nucleic acid by means f a RNA-RNA, RNA-DNA or RNA-PNA interactions and alters the activity of the target nucleic acid. Therefore, for purposes of applying prior art, a short interfering RNA is encompassed in the definition of an antisense compound.

Miyagishi et al. teach gene silencing using siRNA is a very specific process and can be extremely efficient if the siRNA are properly designed. Miyagishi et al. teach an algorithm can predict and identify specific targets sites that are favorable sites for binding of siRNA to initiate interference of gene expression. Miyagishi et al. teach it is advantageous to use an algorithm to design high quality siRNA because an algorithm can predict optimal target sites on a gene (see page 329).

Promega teach design of siRNA using an algorithm wherein the siRNA are capable of interfering with gene expression. Promega teach design of siRNA targeted specifically to nucleotides in the region of 2458-2500 of the human EphB4gene (Genbank accession NM_004444) which encompasses the instantly claimed sequence having SEQ ID No. 231 (see attached sequence). Promega does not teach design of a siRNA comprising chemical modifications such as a 2'-O-alkyl modification and compositions.

Khvorova et al. teach a dsRNA compound, 19 nucleobases in length that is complementary to at least 15 contiguous nucleotides of EphB4 set forth in SEQ ID NO: 392 (see attached sequence alignment and SEQ ID NO: 4253). Khvorova et al. teach the compound is single-stranded that can form a hairpin loop or a double-stranded RNA molecule (see paragraph 0109), wherein the compound comprises one modified backbone or base moieties, wherein the compound has at least one internucleotide linkage, wherein the compound comprises at least one 2'-O-alkylated ribonucleotide (see paragraphs 0136-0138). Khvorova et al. teach pharmaceutical compositions comprising said nucleic acid compounds (see paragraphs 0316).

It would have been obvious to one of skill in the art to use an algorithm, as taught by Promega, to generate a siRNA targeted to a EphB4 gene and further obvious to incorporate chemical modifications as taught by Khvorova et al.

One of skill in the art would have been motivated to generate siRNA against the gene encoding EphB4 using an algorithm given that Miyagishi et al. teach selection of favorable target sites is essential to the efficiency of siRNA and teach the advantage of using an algorithm and further given that Promega et al. provides a publicly accessible algorithm that generates siRNA to any target gene and specifically provides siRNA to the instantly claimed target region comprising SEQ ID No. 231. One of skill in the art would have been motivated to incorporate chemical modifications such as a 2'-O-alkyl because Khvorora et al. teach such modifications increase the compound nuclease resistance.

Finally, one of skill in the art would have had a reasonable expectation of success at generating a RNA duplex targeted to the instantly claimed target sequence SEQ ID No. 231 because Promega et al. specifically teach a method of designing a siRNA targeted specifically to the instantly claimed region and given that generation of said siRNA to is routine to one of skill in the art. One would have had a reasonable expectation of success at incorporating chemical modifications because such modifications are known in the art and routinely used to increase a therapeutic nucleic acids nuclease resistance.

Thus in the absence of evidence to the contrary, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Response to Applicant's Arguments

Re: Claim Rejections - 35 USC § 102 or 35 USC § 103

The rejection of record mailed in the office action 10/31/2006 of claims 1, 3 and 14 are rejected under 35 U.S.C. 102(e) or 35 U.S.C. 103(a) as being anticipated by or obvious over Venter et al. (Patent No: 6,812,339) is obviated is response to amendments filed 04/27/2007.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight

(EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

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Examiner
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